



K111818

JUN 13 2012

510(k) Summary
(per 21 CFR 807.92)

I. Applicant

Ultrasonix Medical Corporation
130 – 4311 Viking Way
Richmond, B.C.
Canada V6V 2K9

Contact Person: Chas Yu, Quality Assurance Manager
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Date Prepared: February 28, 2011

II. Device Name

Proprietary Name: SonixGPS™ Needle Sensor

Classification Name: Ultrasonic pulsed echo imaging system

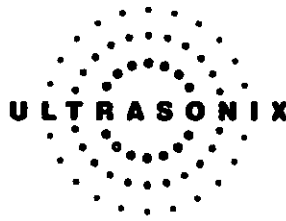
Product Codes: IYO

Classification Regulation: 21 CFR 892.1560

Classification Panel: Radiology

III. Predicate Device

The SonixGPS™ Needle Sensor is substantially equivalent to K092619 -
Electromagnetic Tracking System.



IV. Description of the Device -

The SonixGPS™ Needle Sensor is an electromagnetic sensor that is placed inside a tracked instrument and used within an electromagnetic field. The position and orientation can be detected and combined with the acquired imaging to assist with navigation of the tracked instrument. The needle sensor allows physicians the precise placement of instruments during each procedure by monitoring the real-time trajectory of the instrument as it advances through delicate anatomy to the center of a target.

The needle sensor consists of a sensor head, cable and a connector:

Connector is a positive latching, user-removable interconnect that conducts sensor data from the Cable to the electronics unit.

Cable is the wiring harness for the sensor that conducts sensor data from the Sensor Head to the Connector.

Sensor Head contains a set of coils that make up the measuring element of the sensor assembly.

V. Indications for Use of the Device

The device is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data. The device is available in two models 0.55mm and 0.9mm in diameter.

VI. Technological Characteristics

The SonixGPS™ Needle Sensor has similar construction, manufacturing materials, operating principals and specifications as the predicate device.



Table 1 – Technological Similarities and Differences

	Ultrasonix Medical Corporation	CIVCO Medical
<i>Product Name</i>	SonixGPS™ Needle Sensor	Electromagnetic Tracking System
<i>510(k) Number</i>	-	K092619
<i>Product Code(s)</i>	IYO	IYO
<i>Regulation #</i>	21 CFR 892.1560	21 CFR 892.1560
<i>Class</i>	II	II
<i>Intended Use</i>	The SonixGPS™ Needle Sensor is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data.	The device is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data.
<i>Diameter(s)</i>	0.9 mm and 0.55mm	0.9mm
<i>Length</i>	96.8mm and 110.0mm	177.8mm
<i>Connector (Between Needle Sensor and Accessory)</i>	Luer Lock	Clip on.
<i>Cable</i>	3.8mm OD cable medical grade PVC	same
<i>Connector (Between Needle Sensor and control unit)</i>	metal shell connector	same
<i>Sensor Head</i>	polyimide tubing	same
<i>Intended User</i>	Physician	same
<i>Where Used</i>	Hospital	same
<i>Duration of Use</i>	≤24h	same
<i>Number of Uses</i>	Reusable	same
<i>Sterility</i>	Non-Sterile	same

The additional smaller sensor diameter, difference in sensor length and connection type compared to the predicate device does not affect performance and functionality.



VII. Brief Description of Non-clinical Data

Performance Testing

The following performance test used the same ultrasound system and setup to perform the accuracy test for SonixGPS™ 0.9mm Needle Sensor, SonixGPS™ 0.55mm Needle Sensor and the predicate device.

Test Type	Test Plan	Result
System Accuracy	Based on needle sensor accuracy performance protocol; Sonix 3D Motion Tracking (SonixGPS™) Verification Protocol and Report	The SonixGPS™ 0.9mm Needle Sensor and The SonixGPS™ 0.55mm Needle Sensor demonstrated equivalent performance which met the defined criteria.

The subject devices met the same defined accuracy criteria as the predicate device. The technological differences did not affect the performance of the subject in comparison to the predicate device.

Standards Testing

Applicable Standard or Test Performed	Result
EN 60601-1 (2nd Edition, 1988) Electrical Safety Testing	The SonixGPS™ Needle Sensor met the acceptance criteria.
IEC 60601-1-2 (2.1 Edition; 2001+A1:2004) Electromagnetic compatibility testing	The SonixGPS™ Needle Sensor met the acceptance criteria.
ISO 10993-1:2009 Biological evaluation of medical devices	The SonixGPS™ Needle Sensor met the biocompatibility requirements.



VIII. Conclusion

Ultrasonix Medical Corporation claims the SonixGPS™ Needle Sensor to be substantially equivalent to the predicate device K092619 - Electromagnetic Tracking System, as the SonixGPS™ Needle Sensor has equivalent intended uses, manufacturing materials, operating principles, physical specifications and performance as compared to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ultrasonix Medical Corporation
% Mr. William J. Sammons
Senior Project Engineer - Medical Devices
Intertek Testing Services NA, Inc.
2307 E. Aurora Road, Unit B7
TWINSBURG OH 44087

JUN 13 2012

Re: K111818

Trade/Device Name: SonixGPSTTM Needle Sensor
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO
Dated: June 7, 2012
Received: June 8, 2012

Dear Mr. Sammons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

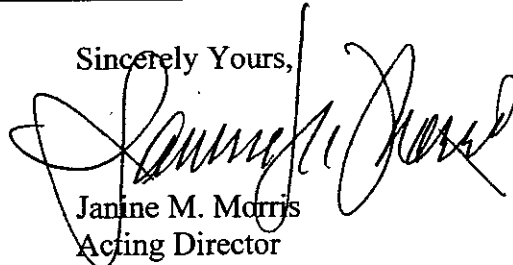
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: SonixGPS™ Needle Sensor

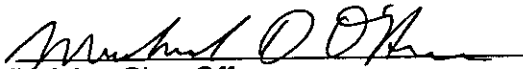
Indications for Use:

The device is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data. The device is available in two models 0.55mm and 0.9mm in diameter.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111818